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Dockets Management Branch (HFA-305) Food and Drug Administration Room 1-23 12420 Parklawn Drive Rockville, MD 20857

RE: Docket No. 97N-0451

Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables

The American Association of Retired Persons (AARP) submits the following comments on FDA's proposed voluntary guidelines to minimize microbial food safety hazards for fresh fruits and vegetables. Recent outbreaks of foodborne illness linked to fresh produce have required a harder look at the growing practices followed both in this country and around the world. The safety of these food products, as well as others, can be a matter of life and death for vulnerable populations -- children, people with suppressed immune systems, and older persons.

The voluntary guidelines for fresh produce proposed by FDA represent another step in the implementation of the President's Safe Food Initiative. AARP believes, however, that the FDA's decision to address the significant food safety problem posed by fresh fruits and vegetables with unenforceable guidelines, rather than enforceable regulations, is a serious misstep. A regulatory system based on the Hazard Analysis and Critical Control Points (HACCP) approach is appropriate here, just as it is for meat and poultry products, and for raw juice products, as FDA itself has recently proposed.

Only through clear, uniform, public-health-based, mandatory standards can the safety of fresh produce be improved. As the number of foodborne illness outbreaks linked to fresh fruits and vegetables continues to increase, as is likely to happen with a system of voluntary guidelines, there is a real possibility that people may reduce their consumption of fresh fruits and vegetables, important components of a healthy diet, and will, instead, choose more processed -- and less nutritious -- foods.

Because illness can result from ingesting even items with a low microbial count, it is imperative that contamination issues be addressed effectively where they begin -- at a farm level -- before produce reaches the consumer. The issue here is not safe handling by the consumer, but, rather, safe cultivation by the farmer.

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In drafting standards, FDA should be as specific as possible to give farmers sufficient guidance. For example, rather than instituting a guideline that says that "potential sources of contamination should be assessed and controlled to the extent feasible," FDA should specify that "a buffer of 500 yards between crops and other animal farms or wildlife refuges should be maintained."

AARP would like to briefly address a number of issues of concern to us in FDA's proposed guide for minimizing the hazards of fresh produce:

There should be "food-specific" safety guidelines. The different ways fruits and vegetables are grown make them subject to different levels of bacterial contamination and therefore necessitate varying approaches to minimizing the microbial hazards. It is generally accepted that fruits and vegetables grown on or in the ground are more vulnerable to direct contact with pathogens than produce grown above ground. AARP urges FDA to develop specific guidelines for each type of produce, including soil-based produce (carrots, potatoes, peanuts, onions, melons, strawberries, and lettuce); vine/pole-grown produce (tomatoes, kiwi, grapes and beans); and orchard fruit (apples, pears, and oranges).

All compost and manure should be sterilized to be pathogen-free. Unsterilized manure and compost are major sources of microbial contamination in the growing process. Contrary to the views of some, compost is not a pathogen-free fertilizer. Therefore, if FDA is going to support its use over that of other fertilizers, like raw manure, then it should be very specific about how the compost must be treated to ensure that it is pathogen-free. We believe that application of a "killstep" (such as pasteurization or other heat treatment) should be required for both compost and manure. Also, while many believe that aging raw manure for sixty days before applying it to the ground ensures that all pathogens have died, others do not agree. FDA should not allow the use of compost containing fecal matter, or any manure containing animal or human feces, that have not been aged for over one year, until science shows that aging should be shorter, longer, or eliminated as an option entirely. In addition, any fertilizer containing aged animal feces must be applied prior to the planting of the crop, not prior to the harvest, in order to ensure the maximal length of time for reduction of organisms.

All water that comes in direct contact with a fruit or vegetable should be pathogen-free. Since nonpotable water is used in agriculture throughout the United States today, it may take quite some time before the goal of a pathogen-free water system for growing produce is achieved. Until that time, nonpotable water should be allowed only for drip irrigating vine/polegrown fruits and vegetables and orchard fruit, where contamination from potential pathogens is indirect, not direct (as it is for soil-based produce).

Compost teas -- created from water that has been poured into a compost heap, which is then sprayed on trees and plants -- must be subjected to the same requirements as compost and manure. They should not be treated like water.

Processing water should be as clean as possible. FDA seems to imply in the proposed guidelines that it is acceptable to use lower quality water early in the process and high-quality water towards the end of processing. However, the dump tanks and flumes in which the produce is washed are the equivalent of the "chill bath" for chicken, in which the pathogens from a single chicken can contaminate hundreds of others. Similarly, in dirty dump tanks and flumes, a piece of fruit can easily spread microbes to dozens if not hundreds or thousands of pieces of fruit. Therefore, these areas must be kept clean through the use of pathogen-free water and frequent sterilization. Moreover, FDA should consider requiring that all produce that can withstand a pressure shower be subjected to one in order to eliminate caked-on larger particles of dirt and mud prior to entering a dump tank or flume of pathogen-free water.

Standards for sanitation and hygiene should be specific. For example, FDA should recommend that all produce-gathering and transporting containers, whether baskets, bags, or cartons, be sanitized at least once a day. Similarly, FDA should set standards that would eliminate the placement of bags, cartons, and containers on the ground, where they are highly likely to come into contact with fertilizers, chemicals, and decomposing organic debris. Similarly, all packing facilities should maintain minimum standards, such as requiring that they be enclosed on all sides and that they have debris-free, solid floors.

We appreciate this opportunity to comment on the proposed voluntary guidelines. If you have any questions, please contact Larry White at (202) 434-3800 in our Federal Affairs staff.

Sincerely,

Martin Corry

Director

Federal Affairs